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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/657,892 | 09/09/2003 | Carl W. Johnson | 1351-008 | 2640 |

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CENTENNIAL, CO 80112

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/657,892 | JOHNSON, CARL W. | |
| | Examiner | Art Unit | |
| | Keith O. Robinson, Ph.D. | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>May 19, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 1 is objected to for its inclusion of blanks (____). It is noted that Applicant has provided an ATCC accession number under the deposit statement (see page 36 of the specification), but Applicant has failed to include this number in claim 1. Applicant is asked to include the appropriate ATCC accession number to claim 1 to overcome this objection.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly drawn to rice seed 'M-206', methods of using said rice seed, and parts thereof.

Since the seed is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112

may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. It is noted that Applicant has deposited the seed of rice variety 'M-206', but there is no indication in the specification as to the access to the invention afforded to the Commissioner upon request nor is there any mention of a test of the viability of the material. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

Claims 8 and 10-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 8 is broadly drawn to a rice plant regenerated from the tissue culture of rice variety 'M-206'. The claim encompasses tissue-culture-derived somaclonal variants of 'M-206', with mutations at one or more genetic loci, which would not possess all the morphological and physiological traits that are inherent in 'M-206'. The specification, however, does not give a written description of such a regenerated plant as to its genetic, morphological, and/or physiological characteristics.

Claims 10-13 are broadly drawn to a hybrid seed and a hybrid plant developed by the crossing of rice plant 'M-206' with another rice plant. The claims seem to include any hybrid plant derived from the crossing of 'M-206' with any rice plant.

The specification does not give a written description of the rice plant that is to be crossed with 'M-206' in terms of its genetic, morphological, and/or physiological composition. It is known in the art that any plant derived from the crossing of two different plants will give a hybrid F1 plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the 'M-206' rice plant and 50% of the alleles from the other, uncharacterized, rice plant. The 'M-206' rice plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the 'M-206' rice plant is not the same as the claimed 'M-206' rice plant, which would have 100% of its alleles. Furthermore, claims 12-13 read on an additional generation of outcrossing to a non-'M206' parent so that seed with as little as 25% of the 'M-206' alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not disclosed in the specification. Since the claimed invention is derived from crossing 'M-206' with any rice plant, there could conceivably be hundreds of hybrids each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids.

Claims 14-21 are broadly drawn to a single gene conversion (claim 14) or transgenic gene conversion (claim 15) of rice variety 'M-206', wherein the introduced gene is dominant or recessive (claims 16-17), confers some type of herbicide or disease or insect resistance (claims 18-20), or confers male sterility (claim 21).

The specification does not give a written description of the single gene conversions as claimed. There is no description of the F1 or subsequent generation

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plants comprising the single gene conversions in terms of their genetic, morphological, and/or physiological composition. There is no description of the introgression of any of the single gene conversions in the claims as to whether or not said introgression should result in successful expression of the desired trait, but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified variety which would disrupt its patentably unique genetic complement. In addition, there is no description of the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny. Furthermore, the multitude of broadly claimed "transgenes" of claim 15 have not been characterized with regard to sequence or conferred trait. The specification does not disclose how to identify the claimed rice plants from a collection of other rice plants.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and

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that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus”. Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claims 8 and 10-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 8 is broadly drawn to a rice plant regenerated from the tissue culture of rice variety 'M-206'. The claim encompasses tissue-culture-derived somaclonal variants of 'M-206', with mutations at one or more genetic loci, which would not possess all the morphological and physiological traits that are inherent in 'M-206'. The specification, however, does not describe of such a regenerated plant with respect to its non-'M-206' traits and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

Claims 10-13 are broadly drawn to a hybrid seed and a hybrid plant developed by the crossing of rice plant 'M-206' with another rice plant. The claims seem to include any hybrid plant derived from the crossing of 'M-206' with any rice plant.

The specification does not disclose or provide guidance for what parents will be crossed with 'M-206' nor does it provide any guidance of the parents' genetic background. It is known in the art that any plant derived from the crossing of two different plants will give a hybrid F1 plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the 'M-206' rice plant and 50% of the alleles from the other, uncharacterized, rice plant. The 'M-206' rice plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the 'M-206' rice plant is not the same as the claimed 'M-206' rice plant, which would have 100% of its alleles. Furthermore, claims 12-13 read on an additional generation of outcrossing to a non-'M206' parent so that seed with as little as 25% of the 'M-206' alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not disclosed in the

specification. Since the claimed invention is derived from crossing 'M-206' with any rice plant, there could conceivably be hundreds of hybrids each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids in terms of their traits, or provide guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

Claims 14-21 are broadly drawn to a single gene conversion (claim 14) or transgenic gene conversion (claim 15) of rice variety 'M-206', wherein the introduced gene is dominant or recessive (claims 16-17), confers some type of herbicide or disease or insect resistance (claims 18-20), or confers male sterility (claim 21).

The specification does not disclose or provide guidance for the single gene conversions as claimed. No guidance has been provided for the obtention of the F1 or subsequent generation plants comprising the single gene conversions, or from where or what said genes are derived. There is no guidance provided for the introgression of any of the single gene conversions in the claims as to whether or not said introgression should result in successful expression of the desired trait, but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified variety which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny. Furthermore, the multitude of broadly claimed "transgenes" of

claim 15 have not been characterized with regard to sequence or conferred trait. The specification does not disclose how to use the claimed rice plants exhibiting a multitude of non-exemplified traits.

While the introgression of single genes into plants for a desired trait is desirable and is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al. (US Patent No. 5,523,520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that did not result in the expected transfer gene trait (see, column 3, lines 26-46). Kraft et al. (Theoretical and Applied Genetics 101:323-326, 2000) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait and that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (see, page 323, column 1, lines 7-15). Eshed et al. (Genetics 143:1807-1817, 1996) teach that epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, pages 1815-1816). Finally, in a study of elite rice hybrids, Yu et al.

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(Proceedings/National Academy of Science 94: 9226-9231, 1997) teach that epistasis plays a significant role in the inheritance of quantitative traits as well as in the genetic basis of heterosis (see, pages 9230, first column, third full paragraph – 9231, last paragraph).

Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in rice breeding materials, such that one or more genes can be transferred from one genetic background to another, wherein the resultant rice progeny would either express the desired trait or maintain all of the other desirable 'M-206' genes and traits.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids, somaclonal variants, single gene conversions, the unpredictability of transferring said genes, and the breadth of the claims, one skilled in the art would not be able to make and/or use the inventions claimed without undue experimentations.

Amending claim 8 to insert the phrase "wherein said plant has all the physiological and morphological characteristics of the rice plant grown from rice seed 'M-206'" before the period would overcome the rejection of this claim under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 14-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 and its dependents are confusing for simultaneously characterizing the rice plant of 'M-206' which possesses particular traits and is male fertile, as simultaneously possessing additional traits and as simultaneously being male sterile.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Bollich et al (Crop Sci. 25:883-885, 1985). The claim reads on somaclonal variants containing mutations at one or more genetic loci of 'M-206', so that the claimed plant reads on any rice plant with any allele at any locus. The claimed method of making the plant (tissue culture of 'M-206') would not confer a unique property to the resultant non-'M-206' rice plant. Bollich et al teach a rice variety that has resistance to several diseases as well as other characteristics (see page 883, second column, third paragraph to page 885, first column, end of first paragraph).

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The rice plant taught by the prior art differs from the claimed rice plants only in their method of making, namely by tissue culturing the exemplified rice inbred. However, the method of making the claimed cotton plant would not distinguish it from the prior art cotton plant. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Amending claim 8 to overcome the rejection under 35 U.S.C. 112, first paragraph, would overcome the art rejection.

Claims 1-7 and 9-21 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified rice inbred which possesses a unique genetic complement and unique collection of traits as that of rice plant 'M-206'.

Conclusion

are
No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

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571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

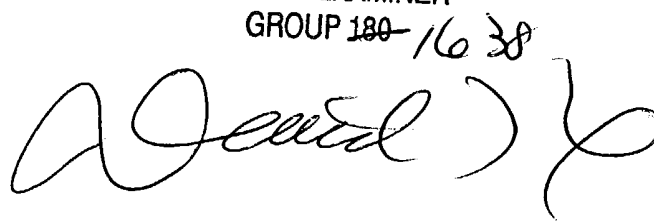
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 18, 2004

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title. The signature is stylized and cursive.